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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/723,520

11/26/2003

Mark R. Andersen

A-71902/AMP/JFB

8934

7590

10/30/2006

DECHERT L.L.P.

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Palo Alto, CA 94304-1106

EXAMINER

PANDE, SUCHIRA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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| 10/723,520   | 11/26/2003  | Mark R. Andersen     | A-71902/AMP/JFB     | 8934             |
| 37509  | 7590        | 06/13/2006           | EXAMINER            |                  |
| DECHERT LLP<br>P.O. BOX 10004<br>PALO ALTO, CA 94303 |             |                      | PANDE, SUCHIRA      |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1637                |                  |

DATE MAILED: 06/13/2006

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**Office Action Summary**

Application No.

10/723,520

Applicant(s)

ANDERSEN ET AL.

Examiner

Suchira Pande

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species:

**A. Species of Quantification Method in claims 4 and 24**

- i. Real time polymerase chain reaction amplification (claims 4 & 24 in part)
- ii. DNA microarray hybridization analysis (claims 4 & 24 in part)
- iii. Electrophoresis (claims 4 & 24 in part)
- iv. Chromatography (claims 4 & 24 in part)

**B. Species of Oligonucleotide probes in claims 9 –10 and 34**

- v. 5' –exonuclease probes (claims 9 in part)
- vi. stem-loop beacon probes (claim 9 in part)
- vii. stemless beacon probes (claim 9 in part)
- viii. plurality of oligonucleotide probes, each of which is complementary to a region of a different amplified target gene sequence of interest (claims 10 & 34).

**C. Species of Assays in claims 35 and 36**

- ix. Single polynucleotide polymorphism analysis (claim 35 in part)
- x. Genotyping analysis (claim 35 in part)
- xi. Gene expression analysis (claim 35 in part)

- xii. Fingerprinting analysis (claim 35 in part)
- xiii. Analysis of gene mutations for genetic diagnoses (claim 35 in part)
- xiv. Analysis of rare expressed genes in cells (claim 35 in part)
- xv. Nucleic acid sequencing (claim 35 in part)
- xvi. Nucleic acid mini-sequencing (claim 35 in part)
- xvii. Chromatography (claim 36 in part)
- xviii. Electrophoresis (claim 36 in part)
- xix. Staining with a dye (claim 36 in part)
- xx. Hybridization probe (claim 36 in part)

The species are independent or distinct because the methods of quantification listed under A are four distinct techniques used in molecular biology based on fundamentally different principles and can also be used to analyze diverse molecules. For e.g. Electrophoresis can be used to separate proteins or DNA or RNA. These 4 species are mutually exclusive.

The probes listed above under B have different structural features /components that are necessary for their ability to function in the specified manner. That is these species are different embodiments, not options or additional features.

The assays listed above under C are distinct methods used to perform different kinds of analysis in molecular biology. For e.g. Gene expression analysis is performed to obtain data about transcription of a gene whereas nucleic acid sequencing is performed to determine the sequence of nucleic acid.

Because these species are distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), searching for all of them together will impose serious search burden, restriction for examination purposes as indicated is proper.

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution from the quantification methods listed under A, the types of probes listed under B, and the Assays listed under C, on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 19, 33 and 40 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

3. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**TERESA STRZELECKA**  
**PATENT EXAMINER**

*Teresa Strzelecka*

*6/9/06*

Suchira Pande  
Examiner  
Art Unit 1637